

KELLEY DRYE & WARREN LLP

A LIMITED LIABILITY PARTNERSHIP

WASHINGTON HARBOUR, SUITE 400

3050 K STREET, NW

WASHINGTON, DC 20007

(202) 342-8400

FACSIMILE

(202) 342-8451

www.kelleydrye.com

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October 2, 2018

VIA FOIAONLINE.REGULATIONS.GOV

George Bollweg, Ph.D.
U.S. Environmental Protection Agency Region 5
Air and Radiation Division
77 West Jackson Boulevard
Mail Code: AT-18J
Chicago, IL 60604-3507
Bollweg.George@epa.gov

**Re: Request for Information Pursuant to the Freedom of Information Act,
40 C.F.R. Part 2 and 2 C.F.R. § 1500.1**

Dear Dr. Bollweg:

This is a request for records of the U.S. Environmental Protection Agency (“EPA”) pursuant to the Freedom of Information Act, 5 U.S.C. § 552, 2 C.F.R. § 1500.1, and 40 C.F.R. Part 2. Please send all responsive records to the following address:

Joseph J. Green
Kelley Drye & Warren LLP
3050 K Street NW
Suite 400
Washington, D.C. 20007-5108
JGreen@KelleyDrye.com

I request all of the research data generated by any researchers conducting research on EPA’s behalf pursuant to Cooperative Agreement Number 83416001 and EPA Contracts EP-11-D-000424 and EP-13-D-000146 (hereinafter “EPA research program). Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues.

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This request does ***not*** extend to any data that might be used to “identify” any of the participants in the EPA research program as set forth in guidance developed by the Department of Health and Human Services (HHS) implementing the protections provided by Health Insurance Portability and Accountability Act (“HIPAA”).¹ The HHS’s De-identification Guidance identifies methods to “de-identify” private health information for a variety of disciplines so that the health data for individuals can be disclosed consistent with HIPAA. One of two methods identified by the De-identification Guidance is a “safe harbor” method. The “safe harbor” method lists 18 different kinds of identifying information that must be removed in order to allow disclosure of private health information for an individual. As the HHS’s De-identification Guidance explains, “the Privacy Rule does not restrict the use or disclosure of de-identified health information, *as it is no longer considered protected health information.*”²

Accordingly, consistent with the HHS’s De-identification Guidance, this FOIA request ***does not extend*** to any of the 18 different items of information that researchers may have generated as part of the EPA research program listed below:

1. Names;
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, SPI code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census: (a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (b) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, and death date.
4. Telephone numbers.
5. Fax numbers.
6. Email addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.

¹ See Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, U.S. Department of Health and Human Services (November 26, 2012) (hereinafter “De-identification Guidance”) available at <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification>.

² *Id.*, p. 6 (emphasis added).

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12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web Universal Resource Locators (URLs).
15. Internet Protocol (IP) addresses.
16. Biometric identifiers, including finger and voice prints.
17. Full-face photographs and any comparable images.
18. Any other unique identifying number, characteristic, or code, except as permitted by guidance allowing for the re-identification of the de-identified health information by the disclosing entity.³

As set forth in the Office of Management and Budget's guidance for financial assistance to non-Federal entities (i.e., 2 C.F.R. § 200.315(e)(1)), the foregoing research was (a) produced under a Federal award and (b) used by the Federal Government in developing agency action that has the force and effect of law in connection with Clean Air Act enforcement proceedings initiated by the United States government on EPA's behalf against S.H. Bell Company. *See United States v. S.H. Bell Company*, Civil Action No. 4:17-cv-00131-BYP, U.S. District Court for the Northern District of Ohio Eastern Division.⁴

If the estimated cost for responding to this request exceeds \$500, please contact me prior to proceeding with the request. I thank you advance for your assistance. If you have any questions concerning this request, please do not hesitate to contact me.

Respectfully submitted,



Joseph J. Green
Counsel to the Manganese Interest Group

cc: National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

³ De-identification Guidance, pp. 7-8

⁴ *See United States' Memorandum in Support of Motion for Entry of Consent Decree* (March 28, 2017) available in PACER: Case: 4:17-cv-00131-BYP, Doc #: 7 Filed 03/28/17 19 of 23 PageID #: 99 ("Nor can there be any real doubt that the peer-reviewed RARE grant health study finding a correlation between manganese exposure and manganism symptoms in East Liverpool residents supported bringing this case.").